

REMARKS

Formal Matters

Claims 17-36 are canceled.

A new claim set is provided. Support for new claims 37 to 44 are provided in the table below. No new matter is added.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Support for new claims

Support for the new claims is found throughout the instant application and parent application 09/062,330 (now 6,897,031) is set forth below.

Claim no.	Element	Support in instant application	Support in parent application
37	general support	Page 3 line 36 to page 4 line 5	Page 3 lines 11-30
37	“introducing”	Page 19, lines 32-34	Page 24, line 29 to page 25, line 2
37	“10 ³ ”	Page 10, line 9	Page 24, lines 25-26
37	“vectors”	Page 19, lines 31-34	Page 25, line 1
37	“mammalian cells”	Page 10, line 20	Page 18, line 22
37	“in vitro”	Page 10 lines 10-12	Page 8, line 27
37	“physiological signal”	Page 9, lines 36-37 Page 34, line 5	Page 8, lines 17-18
37	“at least <i>three</i> optical properties”	Page 4, line 3	Page 3, line 12
37	sequencing to identify	Page 28, lines 10-12	Page 36, lines 5-7

	agent	Page 43, line 20	Page 40, lines 15-20
38	specific physiological signals	Page 34, lines 5-7 Page 20, lines 102	Page 8, lines 17-19
39	“Ca ⁺⁺ and ionomycin”	Page 34, line 6	Page 8, line 18
40	Specific optical properties	Page 34, line 37 Page 34, line 30 Page 10, lines 35-36	Page 9, line 25 Page 7, lines 30-33 Page 7, line 5
41	“10 ⁶ ”	Page 19, line 20	Page 24, line 20
42	“cultured cells”	Page 10, lines 10-12	Page 8, lines 25-26
43	“retroviral vector”	Page 19, lines 36-37	Page 18, line 22
44	“peptide”	Page 16, line 25	Page 21, line 13

Applicants submit that the new claims are fully supported in the instant application *and the parent application.*

The point of prior disagreement between the Applicants and the Examiner, i.e., whether the parent application supported “at least five” FACS parameters is believed be moot because new independent claim 37 recites “at least three” parameters, explicit support for which is found in both the instant application and the parent application (as indicated above).

Rejection under 35 U.S.C. § 103 – Uhr and Conneally

Claims 17-24 and 30 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Uhr (U.S. patent 5,612,185) in view of Conneally (Blood, 1996 87:456-64).

According to the Decision on Appeal, Uhr allegedly discloses a process for treating cancer by arresting the growth of tumor cells, i.e., by placing them in cell cycle arrest (col. 2, lines 62-65). Uhr also allegedly discloses that cell cycle arrest may be induced by gene therapy, e.g., by introducing nucleic acid encoding c-fos or c-jun directly into tumor cells (col. 22, lines 6-10). Uhr allegedly contemplates the use of retroviral vectors (col. 22, lines 14-19), and the production of transgenic mice (col. 22, lines 48-50). Uhr also allegedly discloses analyzing the spleens of mice into which cells have been transplanted by FACS (col. 2, lines 64-65). Conneally is cited solely to highlight the benefits of using of retroviral vectors (page 462, col. 1, middle paragraph).

Uhr's disclosure is deficient for a number of reasons. For example:

- a) Uhr does not teach the use of a library of *at least 10³ vectors encoding different candidate agents*, as required by the rejected claims. Uhr describes the use of a vector that encodes c-jun or c-fos into cells to induce cell cycle arrest. These proteins were chosen by Uhr because they are thought to induce cell cycle arrest. Thus, at best, Uhr suggests a method that employs one of two vectors (which encode c-jun or c-fos). Based on Uhr's disclosure, there would be no reason to use more than two different vectors, let alone at least 1,000 vectors as required by the rejected claims.
- b) Uhr does not introduce candidate agents into cells *and* subject the cells to a physiological signal as separate events, as required by the rejected claims. Uhr merely introduces compounds (c-jun or c-fos) into cells to induce cell cycle arrest. At best, the compounds can either be considered candidate agents (in which case there is no separate physiological stimulus) or as physiological stimuli (in which case there is no candidate agent). Either way, introducing candidate agents into cells *and* subjecting the cells to a physiological signal as separate events is not disclosed by Uhr. Moreover, since the general goal of Uhr's method is to identify compounds that induce cell cycle arrest, at best Uhr teaches an assay that simply involves no more than determining whether a compound causes a cell to arrest. That is not the method being claimed.
- c) Uhr does not disclose using FACS to examine the individual cells in the cell population that has been grown *in vitro*. The only FACS methods described in Uhr's disclosure are those in which the cells of spleens of animals are examined. Such cells are grown *in vivo* rather than *in vitro* and, as such, this element of the claims is not provided.
- d) Uhr does not disclose sequencing the nucleic acid encoding the candidate agent in a cell that has an altered phenotype. Since the identities of Uhr's clones (which, at best would encode c-jun or c-fos) would be known before any experiments were initiated, there would be no need for this step to be performed.

None of the above deficiencies is met by Conneally's suggestion to use retroviral vectors and, as such, taken in any combination, Uhr and Conneally fails to teach or suggest all of the elements of the rejected claims.

The Applicants submit that this rejection has been adequately addressed. Withdrawal of this rejection is requested.

Rejection under 35 U.S.C. § 103 – Nolan in view of Jia-Ping and Uhr

Claims 17-25, 30 and 32 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Nolan (WO 97/27212) in view of Jia-Ping and Uhr. The Applicants respectfully traverse this rejection.

The issue resolved in appeal was whether the instant application was entitled to claim priority to parent application serial no. 09/062,330, now issued as U.S. patent 6,897,031, for claims that recited “at least five” FACS parameters.

New claim 37 recites “at least three” parameters, explicit support for which is found in both the instant application (e.g., at page 4, line 3) and the parent application (e.g., at page 3, line 12). Likewise, support for the remainder of the elements of the instant claims is found in the parent application (see table above).

A Declaration under 35 U.S.C. § 1.131 (the “Fisher declaration”; attached as Exhibit A) was previously submitted with the Applicants’ response of July 24, 2006, in order to obviate a rejection over a near identical combination of references (i.e., Nolan in view of Jai-ping *or* Ryan). The Fisher Declaration established invention of the subject matter of the rejected claims prior to the Nolan’s publication date.

The Applicants’ prior arguments were deemed unpersuasive by the Board solely because the parent application allegedly does not support claims that recited “at least five” FACS parameters. Because the new claims recite “at least three” parameters (an element that is explicitly supported in the instant application and the parent application; see above), the priority claim of the instant application is proper, and the Fisher Declaration is believed to show prior conception of the claimed invention prior to Nolan’s publication date. Thus, Nolan cannot preclude the patentability of the rejected claims.

The Examiner is respectfully requested to review the arguments set forth on pages 9-11 of the Applicants’ response of July 24, 2006, in the context of the new claims, and withdraw this rejection.

Withdrawal of this rejection is requested.

With the above in mind, the Applicants note that MPEP §§ 715.02¹ and 715.03² explicitly state that a showing of completion of a single species encompassed by a genus claim is sufficient to antedate

¹ MPEP § 715.02.I: “applicant’s 37 CFR 1.131 affidavit must show possession of something falling within the claim(s) prior to the effective date of the reference being antedated”. MPEP § 715.02.II: “a reference or activity applied against generic claims may (in most cases) be

a reference. As such, according to the MPEP, the Fisher Declaration need not show completion of every species within the claimed genus for this rejection to be withdrawn.

To the extent that any further discussion is necessary, the Examiner is referred to the Applicants' response of February 24, 2006.

Withdrawal of this rejection is requested.

Rejection under 35 U.S.C. § 103 – Nolan in view of Jia-Ping, Uhr and Hide

Claim 26 is rejected under 35 U.S.C. § 103 as unpatentable over Nolan in view of Jia-Ping, Uhr and Hide. The Applicants respectfully traverse this rejection.

As discussed above, Nolan's publication date is antedated by the Inventors' activities.

As such, Nolan cannot preclude the patentability of the rejected claims, and this rejection should be withdrawn.

antedated as to such claims by an affidavit or declaration under 37 CFR 1.131 showing completion of the invention of only a single species, within the genus, prior to the effective date of the reference or activity.....”

² MPEP § 715.03.II: “In general, where the reference or activity discloses the claimed genus, a showing of completion of a single species within the genus is sufficient to antedate the reference or activity under 37 CFR 1.131. Ex parte Biesecker, 144 USPQ 129 (Bd. App. 1964).”

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-036CIP.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: September 16, 2010

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Exhibit A: Fisher Declaration of response of July 24, 2006

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